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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/878,034

06/08/2001

Daniel McTeigue

MCP-0279

1620

27777

7590

03/31/2003

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EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/31/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/878,034

Applicant(s)

MCTEIGUE ET AL.

Examiner

Amy E Pulliam

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Receipt of Papers*

Receipt is acknowledged of the Extension of Time and the Amendment A, both received by the Office on January 27, 2003.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Canadian Application 2,068,366 to Morella *et al.*.

Morella *et al.* disclose a taste masked free flowing powder including microcapsules, wherein each microcapsule includes an effective amount of a core element including at least one pharmaceutically active ingredient, a substantially smooth and continuous microcapsule coating on the core element formed from a coating composition including a water insoluble polymer (p 25, claim 1). Morella *et al.* teach that this polymer is ethyl cellulose (p 25, claim 7). Furthermore, Morella *et al.* teach that the active agent can be a non-steroidal anti-inflammatory agent (p 25, claim 5). Morella *et al.* also teach the tasted masked free flowing powder composition discussed above, wherein the coating composition includes a water insoluble polymer (ethyl cellulose) and a polymeric component which can be an enteric polymer (p 26, claim 9). In their disclosure, Morella *et al.* teach that enteric polymers include cellulose acetate

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phthalate, hydroxypropyl methyl cellulose phthalate, hydroxypropyl methyl cellulose acetate succinate, and others (p 9, l 30-38). Additionally, Morella *et al.* teach that the coating comprises a water insoluble polymer, and one or more of an enteric polymer, an acid-soluble polymer, and a partially water soluble polymer (p 26, claim 9). The reference also allows for the inclusion of excipients (p 11, l 23-32). Morella *et al.* also teach that the taste masked free flowing powder can be in the form of a chewable tablet (p 29, claim 28).

Morella *et al.* do not teach the particular release profile claimed by Applicant. However, it is the position of the examiner that because Morella *et al.* teach the same ingredients as Applicant, it would flow that Morella *et al.* would have the same release profile as Applicant. The burden is shifted to Applicant to provide evidence that the two compositions exhibit different profiles, if this is the characteristic to be relied upon to show patentable distinction. Absent such evidence, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant argues that the Canadian Application does not teach or suggest combinations of enteric polymers and water insoluble film forming polymer to obtain immediate release type dissolution profiles, which is an aim of Applicant's invention. The examiner finds this argument to be unpersuasive for several reasons. First, the claims do not state that they have immediate release type dissolution profiles, this language is not expressly stated in the claims. Second, the claims are drawn to compositions, rather than methods, and therefore, that the aim of Applicant's invention is to create immediate release profiles is not persuasive, unless it can be clearly shown

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that there are differences in the actual composition. Additionally, Applicant has amended the claims to include a particular release rate when tested according to a particular method in a particular pH. Applicant argues that the reference does not have the same profile, and Applicant relies on the reference's teaching that less than 80% of the drug is released after 30 minutes in a pH 7.5 solution. The examiner points out that this is an unfair comparison, as Applicant is testing his dissolution rate in a pH of 7.2. It is entirely possible that the slight difference in dissolution profiles could be a result of this pH difference. Furthermore, The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). If Applicant wishes to rely on the dissolution profile to show patentable distinction, it is recommended that Applicant supply experimental data, showing Applicant's instant formulation and the reference's formulation, tested under identical circumstances. Absent such comparative analysis, it is impossible to state with certainty that the reference has a difference release profile. For these reasons, the above rejection is maintained.

### ***Conclusion***

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam  
March 26, 2003

THURMAN K. PAGE  
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